United States Senate
WASHINGTON, DC 20510

February 23, 2006

The Honorable Michael O. Leavitt
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Leavitt:

We are writing to express our concern about the final rule published on January 18, 2006 in the Federal Register amending 21 CFR parts 201, 314, and 601. The rule modifies drug labeling requirements in order to give information to physicians in a more concise and appropriate manner. We certainly support such an initiative, and believe it will help physicians provide better care to their patients.

However, the preamble to the final rule asserts broad and vague federal preemption of state drug labeling, advertising, and product liability laws. Such an assertion is inconsistent with long-standing Food and Drug Administration practice and Congressional intent. In fact, the preamble to the proposed rule, published in the Federal Register on December 22, 2000, explicitly stated that "this proposed rule does not preempt state law." At the very least, such a drastic reversal of policy with such far-reaching implications should be subject to public consideration and an opportunity for comment on whether the agency has the legal authority to preempt state requirements.

We strongly believe that states have an important role to play in protecting consumers and patients from unsafe drugs, and question the notion that the FDA alone can provide this protection. As a former Governor, you understand that important advances in public health and safety have been achieved at the state level. This new FDA claim of preemption would undermine state laws, even in cases where those laws address an area where FDA has not acted, and would smother the ability of states to take reasonable steps to protect public health and the safety of their citizens. Given recent questions about FDA's ability to ensure the safety of prescription drugs, it is a particularly inopportune time to remove the safety net that state consumer protection laws provide.

We are somewhat comforted by reports that Scott Gottlieb, Deputy Commissioner for Medical and Scientific Affairs at the FDA, has stated that the preamble assertion that State product liability claims are preempted by FDA regulation of prescription drug labeling is not legally binding. This statement is consistent with the agency's regulations, which state that a preamble statement is an advisory opinion under 21 CFR 10.85(d)(1) that "may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement," as provided under

21 CFR 10.85(j). However, Dr. Gottlieb's statement notwithstanding, further clarification of the Administration's intent is necessary. We respectfully request that you provide answers to the following questions no later than March 31, 2006.

1. When Congress enacted the Federal Food, Drug, and Cosmetic Act in 1938, it specifically rejected a proposal to include a private right of action for damages caused by faulty or unsafe products regulated under the Act, on the ground that such a right of action already existed under state common law. *See, e.g.*, Hearings before Subcommittee of Committee on Commerce on S. 1944, 73d Cong., 2d Sess. 400, 403 (1933); Adler & Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. 895, 924 & n.130 (1995).

   In section 202 of the Drug Amendments of 1962, Congress stated that "[n]othing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." Since 1938, Congress has never chosen to preempt State product liability actions through amendments to the Act.

   Given these unambiguous statements of Congressional intent, please explain—
   (a) Why the agency completely ignores the clear legislative history that Congress intended State product liability actions to survive under the federal law, and
   (b) why a statutory statement that state law is preempted only in cases of "direct and positive conflict" does not control the agency's contrary interpretation of the law.

2. In the December 2000 proposed rule, the agency stated that the regulation would not preempt state law. In the preamble of the final rule, on pages 43 and 44, the agency cited only three specific FDA regulatory requirements – all with respect to over-the-counter products – that FDA has described in preambles from before 2000 as preempting State law. These examples suggest that FDA has pursued preemption only narrowly in the past. Yet the final preamble asserts that it has been the government's "longstanding" position that state actions related to drug labeling and advertising, and even medical malpractice, are preempted. Please explain this dubious assertion and provide all agency statements before 2001 with respect to this issue.

3. Under Executive Order 13132, issued by President Reagan and reissued by President Clinton, a federal agency such as FDA must consult with State and local authorities about, and examine, the effects on States and localities of each regulation it issues. In the proposed rule, FDA indicated that the regulation would not preempt State law. We understand that, relying on this representation and their own analyses of the proposed rule, the States did not comment on it. Please

describe what the agency did to consult with State and local governments about this regulation.

4. FDA justifies its sweeping preemption argument by making a number of seriously misleading assertions about the comprehensive nature of the agency's review of safety and effectiveness information and the adequacy of the disclosure of risks and benefits on the drug label. Perhaps the most significant and troubling misrepresentation of FDA's regulation of the drug label is the claim that, after approval, the approved drug label continues to provide, on a timely basis, comprehensive information about the risks and benefits of the drug. The preamble at page 39 also strongly implies that FDA can immediately require the inclusion of new information in a drug label whenever the agency decides disclosure of such information is warranted. Neither of these assertions is true, however.

   Important information about how to use a drug safely and effectively that is developed after approval is not always added to the drug's label in a timely way, because FDA has very limited authority to require the collection of such information or require its timely inclusion in the label. Although the agency monitors reports of adverse events after approval, such reports rarely provide definitive evidence of risks, and additional studies are often needed to confirm and define any risks that are signaled by adverse event reports. After approval, however, FDA cannot, except in narrow cases, require a drug company to study further benefits and risks. When such studies are conducted voluntarily, they often take years to complete, if they are completed at all.

   More importantly, the label is owned by the manufacturer, and FDA cannot require a company to change the label, short of initiating a lengthy court proceeding or withdrawing the drug from the market. Both of these options take months or even years. In practice, this inability to require immediate changes in the label means the agency must negotiate changes in the drug label with the drug manufacturer. As a result, manufacturers can delay for months before adding important new risk information to a drug's label, and can water down the language requested by FDA. For example, it took more than 18 months for Merck to add new information about cardiac risks to the label of Vioxx.

   Is the agency now claiming that it has the authority to require manufacturers to conduct post-approval studies to assess newly discovered risks, or that it has authority to require immediate label changes? If not, what is the basis for FDA's argument that the drug label always contains up-to-date information on newly discovered risks? Is it FDA's position that the Vioxx label at all times contained information that correctly described FDA's view of the risks of that drug? Would claims be preempted that Merck failed to warn patients who used Vioxx?

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If you have any questions about this request, please do not hesitate to let us know, or have you staff contact Ben Berwick with Senator Dodd (224-5484) or David Bowen with Senator Kennedy (224-7675). Thank you for considering this important request on drug labeling, and we look forward to your reply.

With respect and appreciation,

Edward M. Kennedy
United States Senator

Christopher J. Dodd
United States Senator